

REMARKS/ARGUMENTS

Supplemental Amendment

Claims 19-21 and 23-30 are pending in the present application. Claims 20, 23 and 24 have been currently amended. New Claims 29 and 30 have been added. Applicants respectfully submit that two claims were inadvertently numbered "22" in the claim set of the Preliminary Amendment filed November 25, 2003. These claims have now been canceled, and replaced with new claims 29 and 30, as added to the present amendment. Claim 20 was amended to correct typographical errors. Claims 23 and 24 were amended to correct the respective dependency of each claim. Support for the new and amended claims can be found throughout the specification and in the original claims. No new matter is believed to have been introduced by amended and new claims.

Applicants' undersigned representative would like to thank the Examiner for the telephone discussion on June 14, 2004. During this discussion, Applicants' representative discussed the fact that two claims were numbered "22," and that the claim count would be corrected in a Supplemental Amendment filed with the Response to Restriction Requirement. Applicants' representative also mentioned that it appears that the subject matter of both of the claims denoted as "Claim 22" would belong to Group II of the present Restriction Requirement. Therefore, it now appears that both new Claims 29 and 30 belong to Group II of the present Restriction Requirement.

Response to Restriction Requirement of May 26, 2004

The Office has required restriction of the claims as filed in the Preliminary Amendment of November 25, 2003, into the following groups:

- I. Claims 19, 25 and 26, drawn to a hybrid protein, compositions comprising said hybrid protein and methods of immunizing, comprising administering said hybrid protein.
- II. Claims 20-22, drawn to a recombinant method of making a protein using a transformed microorganism, the transformed host.
- III. Claims 23, 24, 27 and 28, drawn to compositions/pharmaceutical compositions comprising transformed hosts and methods of immunizing using said recombinant host cell.

Applicants elect, with traverse, Group I (Claims 19, 25 and 26) for further prosecution.

The Examiner has characterized the inventions of Group I and Group II/II, as drawn to products that are biologically, chemically and structurally different, as noted in the present Office Action on page 2. The Examiner has also characterized these Groups as related to a process of making and product made, and in which the product can be made by another means, as noted on page 2 of the present Office Action. The Examiner characterized the inventions of Groups II and III as comprising two different methods, and as comprising products that can be used for materially different processes, as noted on page 3 of the present Office Action. Thus the Examiner required restriction among the above groups. Applicants respectfully traverse based on the following reasons.

Applicants submit that the Office has not made a proper restriction. Restriction is only proper if the claims of the restricted groups are either independent or distinct. There also must be a serious burden on the Examiner if restriction is required. The burden of proof is on the Office to provide reasons and/or examples to support any conclusion in support of restriction (see MPEP § 803). Applicants respectfully submit that the Office has not

supported its conclusion of restriction, and has not demonstrated that it would be a serious burden to examine the entire application.

In distinguishing the claims of Groups I and II/III, the Examiner provided only a general statement that the products of these groups are biologically, chemically and structurally different, and therefore are patentably distinct and independent inventions. However, the Examiner did not provide any reasons or examples, in terms of, for example, a description of such differences, to support this statement. In addition, the Examiner provided a general statement that the hybrid protein of Group I can be made by other means than recombinant, i.e., proteins can be naturally isolated and conjugated together. However, the Examiner did not provide any reasons or examples, in terms of, for example, a description of such an isolation and conjugation procedure, to support this statement.

Moreover, the Examiner provided only a general statement that the Inventions of Groups II and III comprise different methods, i.e., a method of recombinantly producing proteins and a method of inducing an immune response in a mammal. However, the Examiner did not provide any reasons or examples, in terms of, for example, a description of such differences, to support this statement. Also, the Examiner made a general statement that these groups comprise products that can be used for materially different processes, i.e., the pharmaceutical composition of Group III contains an adjuvant and is used in immunization methods, whereas the recombinant microorganism of Group II is used to produce proteins. However, the Examiner did not provide any reasons or examples, in terms of, for example, descriptions of such an immunization and protein synthesis, to support this statement.

Therefore, the Office has not supported its conclusion of restriction of the respective groups, and has not shown that it would be a serious burden to search and examine these groups together. Applicants submit that a search of all the claims would not impose a serious burden on the Office.

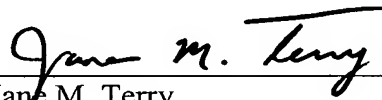
Applicants also respectfully submit that if the elected product claims are found allowable, withdrawn method claims should be rejoined under MPEP § 821.04, if the method claims depend on, or include all the limitations of, the allowed product claim.

Accordingly, for at least the reasons presented above, Applicants submit that the Office has failed to meet the burden necessary, in order to sustain the requirement for restriction in the present application. Applicants respectfully request the withdrawal of the Restriction Requirement.

Applicants respectfully submit that the present application is now in condition for examination on the merits, and earnestly request early notice of such action.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
Norman F. Oblon



Jane M. Terry  
Registration No. 53,682

Customer Number  
**22850**

Tel: (703) 413-3000  
Fax: (703) 413-2220  
(OSMMN 06/04)